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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,677	08/16/2006	Daria Onichtchouk	2923-769	8404
6449 7590 01/09/2008 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			EXAMINER HILL, KEVIN KAI	
			ART UNIT 1633	PAPER NUMBER
			NOTIFICATION DATE 01/09/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

## Office Action Summary

**Application No.**

10/589,677

**Applicant(s)**

ONICHTCHOUK, DARIA

**Examiner**

Kevin K. Hill, Ph.D.

**Art Unit**

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2, 9-10, 12-22, drawn to a pharmaceutical composition comprising a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein, or functional fragment thereof.

Group II, claims 1-22, drawn to a pharmaceutical composition comprising a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group III, claims 1-22, drawn to a pharmaceutical composition comprising an effector/modulator of a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group IV, claims 1-2, 9-10, 12-22, drawn to a pharmaceutical composition comprising an effector/modulator of a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group V, claims 1-22, drawn to a pharmaceutical composition comprising a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein, or functional fragment thereof, and a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group VI, claims 1-2, 4-10, 12-22, drawn to a pharmaceutical composition comprising a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein, or functional fragment thereof, and an effector/modulator of a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group VII, claims 1-2, 9-10, 12-22, drawn to a pharmaceutical composition comprising a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein, or functional fragment thereof, and an effector/modulator of a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group VIII, claims 1-22, drawn to a pharmaceutical composition comprising a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein, or functional fragment thereof, and an effector/modulator of a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group IX, claims 1-2, 4-10, 12-22, drawn to a pharmaceutical composition comprising a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein, or functional fragment thereof, and an effector/modulator of a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group X, claims 1-2, 4-10, 12-22, drawn to a pharmaceutical composition comprising an effector/modulator of a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof, and an effector/modulator of a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group XI, claims 1-22, drawn to a pharmaceutical composition comprising a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein, or functional fragment thereof, a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof, and an effector/modulator of a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group XII, claims 1-22, drawn to a pharmaceutical composition comprising a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein, or functional fragment thereof, a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof, and an effector/modulator of a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group XIII, claims 1-22, drawn to a pharmaceutical composition comprising a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein, or functional fragment thereof, an effector/modulator of a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof, and an effector/modulator of a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group XIV, claims 1-22, drawn to a pharmaceutical composition comprising a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein, or functional fragment thereof, an effector/modulator of a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof, and an effector/modulator of a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof.

Group XV, claims 1-22, drawn to a pharmaceutical composition comprising a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein, or functional fragment thereof, a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof, an effector/modulator of a nucleic acid molecule encoding a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof, and an effector/modulator of a SF01, SF02, SF03, SF04, SF05, SF06, SF07, SF08, SF09, SF10, SF11, SF12 or SF13 protein or a functional fragment thereof..

Group XVI, claim 23, drawn to a method of using a pharmaceutical composition for the manufacture of a medicament for the treatment of disease.

Group XVII, claim 24, drawn to a method of identifying substances capable of interacting with a SF polypeptide.

Group XVIII, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF01 polypeptide.

Group XIX, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF02 polypeptide.

Group XX, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF03 polypeptide.

Group XXI, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF04 polypeptide.

Group XXII, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF05 polypeptide.

Group XXIII, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF06 polypeptide.

Group XXVI, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF07 polypeptide.

Group XXV, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF08 polypeptide.

Group XXVI, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF09 polypeptide.

Group XXVII, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF10 polypeptide.

Group XXVIII, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF11 polypeptide.

Group XXIX, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF12 polypeptide.

Group XXX, claims 25-28, drawn to a transgenic animal exhibiting increased expression of a SF13 polypeptide.

Group XXXI, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF01 polypeptide.

Group XXXII, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF02 polypeptide.

Group XXXIII, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF03 polypeptide.

Group XXXIV, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF04 polypeptide.

Group XXXV, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF05 polypeptide.

Group XXXVI, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF06 polypeptide.

Group XXXVII, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF07 polypeptide.

Group XXXVIII, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF08 polypeptide.

Group XXXIX, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF09 polypeptide.

Group XXXX, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF10 polypeptide.

Group XXXXI, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF11 polypeptide.



Group XXXXII, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF12 polypeptide.

Group XXXXIII, claims 25-28, drawn to a transgenic animal exhibiting reduced expression of a SF13 polypeptide.

Group XXXXIV, claim 29, drawn to a method of identifying a polypeptide involved in the regulation of energy homeostasis and/or metabolism in a mammal.

Group XLV, claim 30, drawn to a method of screening for an agent which effects/modulates the interaction of an SF polypeptide with a binding target.

Group XLVI, claim 31, drawn to a method of screening for an agent which effects/modulates the activity of an SF polypeptide.

Group XLVII, claim 32-34, drawn to a method of producing a composition comprising mixing a polypeptide involved in the regulation of energy homeostasis and/or metabolism in a mammal with a pharmaceutically acceptable carrier and/or diluent.

Group XLVIII, claim 35, drawn to a method of using a nucleic acid molecule encoding an SF polypeptide for the preparation of a medicament.

Group XLIX, claim 36, drawn to a method of using an SF polypeptide for the preparation of a medicament.

Group L, claim 37, drawn to a method of using a vector for the preparation of a medicament.

Group LI, claim 38, drawn to a method of using a host cell for the preparation of a medicament.

Group LII, claim 39, drawn to a method of using an SF nucleic acid molecule for the production of a non-human transgenic animal.

Group LIII, claim 40, drawn to a kit.

Group LIV, claims 41-42, drawn to a method of producing a composition comprising mixing an agent which effects/modulates the interaction of an SF protein with a binding target with a pharmaceutically acceptable carrier and/or diluent.

2. The inventions listed as Groups I-LIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the specification discloses that SF01-SF13 corresponds to mammalian proteins described in Table 1 (pgs 18-19), wherein each is a structurally and biologically different protein. The specification also discloses that SF11 is well-characterized (pg 7, lines 6-7), for example, and thus SF11 does not contribute over the prior art. The claimed methods do not share a special technical feature because each method requires different process steps, require the use of different reagents and have different objectives. Furthermore, inventions XLVII and LIV use compounds not yet discovered as a result of performing screening methods. Hence, the special technical features of such as yet to be discovered compounds do not share the same special technical features of Groups I-XV, XVIII-XXXXIII and LIII.

3. In addition, inventions I-XV detailed above reads on patentably distinct inventions drawn to a plurality of SF proteins or nucleic acids encoding said SF proteins. The claimed SF proteins do not share a common structure or activity.

**In response to the restriction requirement, Applicant must further elect a specific SF protein and/or a specific nucleic acid molecule encoding said specific SF protein, selected from the group consisting of SF01-SF13.**

It is further noted that this is a restriction requirement and should not be construed as an election of species.

Inventions I-XV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (protein-nucleic acid, protein-modulator of nucleic acid, protein-modulator of protein, nucleic acid-modulator of nucleic acid, nucleic acid-modulator of protein, etc...) claimed does not require the particulars of the subcombination as claimed because the other components in each instance could lend patentability to the combination. The subcombination has separate utility such as identifying SF protein-binding molecules without the presence of the nucleic acids, as indicated in invention groups XLV-XLVI, respectively.

The Examiner has required restriction between combination and subcombination inventions. Where Applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions I-XV, Inventions XVIII-XXXXIII and Invention LIII are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are materially different in chemical structure and biological function. Each transgenic organism inherently possesses a distinctly different genotype and distinctly different phenotype due to the over- or under-expression of the claimed SF protein. The compositions comprise compounds possessing distinctly different biological activity, e.g. nucleic acid-binding protein, small molecules, antibodies or proteins. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I-LVII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, each of the claimed methods of use may be practiced with distinctly different products, set forth above, so as to yield distinctly different results, e.g. screening for an unknown compound, making a transgenic animal, synthesizing a new pharmaceutical composition, etc...

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;

- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, Applicant must indicate which of these claims are readable upon the elected invention.

Should Applicant traverse on the ground that the inventions are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of

the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

**4. This application contains claims directed to the following patentably distinct species:**

- i) SF proteins, as recited in claims 23-24, 29-31, 35-36 and 39,
- ii) nucleic acid molecules, as recited in claims 23-24, 35, 37 and 39,
- iii) diseases, as recited in claims 23, 33-38 and 42,
- iv) test compounds, as recited in claim 24,
- v) assay setting (in vitro or in vivo), as recited in claim 24, and
- vi) specific combination of kit components, as recited in claim 40.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species

lack the same or corresponding special technical features. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed species from (i), (ii), (iii), (iv), (v) **and** (vi) **according to the elected invention** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.**

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

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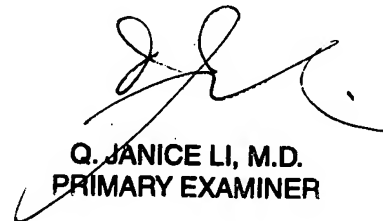
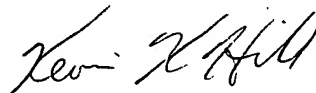
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Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Q. JANICE LI, M.D.  
PRIMARY EXAMINER